

5. 510(k) Summary as required by 21 CFR§807.92(c)

510(k) Owner: FCI SAS (France Chirurgie Instrumentation) AUG 3 2012
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Date: November 29, 2011

Trade Name: MASTERKA 40
MASTERKA 35
MASTERKA 30

Common name: Monocanalicular Lacrimal Stent
Lacrimal Intubation Set

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device

The MASTERKA® is substantially equivalent to the Mono-Crawford Naso-Lacrimal Intubation Device marketed by FCI Ophthalmics, Inc, 510(k) Premarket Notification Number: K061404, FDA Product Code OKS; and, to the Mini-Monoka monocanalicular probes marketed by FCI Ophthalmics, Inc, 510(k) Premarket Notification Number: K061404, FDA Product Code OKS.

General Description

The MASTERKA® is a monocanalicular intubation device with self-retaining punctal fixation for the treatment of stenoses that require intubation. The device consists of a silicone tube molded to a fixation head and pre-mounted on an introducer. The introducer facilitates insertion of the MASTERKA and is completely removed once the intubation of the lacrimal passages has been completed. The MASTERKA® comes in three different lengths (30, 35, or 40 mm depending on the model) and is provided as a sterilized product.

Indications for Use

The MASTERKA® is a silicone intubation device indicated for use in the treatment of congenital lacrimal duct obstructions (stenosis of the valve of Hasner) in patients 12 months and older.

Comparison of Technological Characteristics

The MASTERKA® and the Mono-Crawford Naso-Lacrimal Intubation Device and Mini-Monoka predicate devices all have the same basic indications for use, intended use, and intubation method. All three devices have a stent body (tube) that is manufactured from medical grade silicone, although the predicate device tubes are cut from a silicone tube; whereas, the MASTERKA is molded from silicone. All three devices have a punctal plug that anchors the device, and which is made of medical grade silicone that is molded and polished to the finished size and shape. All three devices are manufactured using the same processes. The finished MASTERKA® and predicated devices are ethylene oxide sterilized and provided in similar packaging.

The primary differences between the MASTERKA® and the predicates are the dimensions of the stent body (tube) and the method for introducing the device into the punctum. The MASTERKA® is pre-loaded onto a stainless steel introducer to facilitate its insertion; whereas, the Mono-Crawford device is introduced via a stainless steel guide. The Mini-Monoka is not supplied with a guide or introducer. The MASTERKA® external/internal diameters are slightly larger than the predicate devices and published literature supports the clinical safety and effectiveness of the larger MASTERKA® external/internal diameters. (See Clinical Testing)

NonClinical Testing

The MASTERKA® device has been designed and tested to the applicable standards. All nonclinical test results met the established specifications for the device. In-process controls and final product quality controls, including finished product release testing and inspection, assure that the MASTERKA is manufactured within specifications. The biocompatibility of the silicone raw materials and finished, sterilized device was tested to the applicable standards and met

required specifications, confirming that the MASTERKA® device can be implanted for periods longer than 29 days. Ethylene oxide sterilization validation studies and package integrity studies were performed according to the applicable standards; and, the test results support the shelf-life and storage conditions for the device.

The results from the nonclinical testing demonstrate the MASTERKA® device meets the established specifications for the device and that the test results and established specifications are substantially equivalent to those of the MASTERKA® and the Mono-Crawford Naso-Lacrimal Intubation Device and Mini-Monoka predicate devices.

Clinical Testing

Published literature supports the clinical safety and effectiveness of the device for its intended use. Fayet et al. published the results of a series of 90 cases of MASTERKA intubation for the treatment of nasolacrimal duct obstruction.¹ Of these, 68 cases underwent a MASTERKA® for congenital lacrimal duct obstructions in patients 12 months and older (age range 1 to 9 years). The pediatric results are presented below in support of the MASTERKA®'s intended use in this patient population.

The MASTERKA® devices that were implanted in the 68 cases were identical to the MASTERKA® device that is cleared for marketing in the United States; and, the indications for treatment in all 68 cases were consistent with the MASTERKA®'s intended use as a silicone intubation for congenital nasolacrimal duct obstruction in patients 12 months of age and older. Performing a nasolacrimal probing is essential for selection of the proper intubation device. Each of the 68 cases had a nasolacrimal probing performed prior to the MASTERKA® intubation that confirmed each stenosis to be simple in complexity and located at the valve of Hasner. The MASTERKA® intubation was then performed using the "push" technique described in the MASTERKA instructions for use, with the location of the silicone intubation verified endoscopically (n = 6 cases) or by metal-to-metal contact (n = 62 cases). A punctum plug inserter was used to seat the anchoring fixation head for each implanted MASTERKA® device.

No postoperative epistaxis occurred in any of the 68 cases (0/68; 0/0%) that were implanted with the MASTERKA®, and no intraoperative or postoperative systemic complications were reported. The overall success rate for simple nasolacrimal intubation at the valve of Hasner, defined as absence of epiphora and mucous discharge, was 89.4% (60/66 cases successful; 2 cases lost to follow-up at 1 day and 7 days). The complication rate was 13.2% (9/68 cases); and, complications consisted of early tube loss (8/68; 11.8%) at 1 day (n=6) or 7 days (n=2) postoperatively, and one report of keratitis (1/68; 1.5%) in an intubation with a duration of 1 day. Of the 8 cases of early stent loss, 5 (5/8; 62.5%) were still considered to be successful intubations.

¹ Fayet B, Racy E, Ruban J-M, Katowitz J. Pushed monocanalicular intubation. Pitfalls, deleterious side effects, and complications. *Journal Français d'Ophtalmologie* (2011) 34, 597—607.

The authors concluded that the MASTERKA® intubation technique was simpler to perform and caused less nasal trauma (as evidenced by no reports of postoperative epistaxis) than the traditional intubation techniques that are used with the predicate devices and require nasal retrieval of the intubation tubes. The complication types and rates are similar to other nasolacrimal intubation devices, including the predicate devices, with the most commonly occurring MASTERKA® complication being early stent loss.

Basis of Substantial Equivalence

The MASTERKA® is substantially equivalent to the Mono-Crawford Naso-Lacrimal Intubation Device and Mini-Monoka in medical grade silicone materials used to manufacture the device, intended use as a silicone intubation device for the treatment of congenital lacrimal duct obstructions, basic design concept consisting of a stent body (tube) and anchoring plug, internal and external dimensions, ethylene oxide sterilization methods, biocompatibility of the silicone raw materials and finished devices, and storage conditions; and, which are all manufactured by FCI SAS and distributed in the U.S.A. by FCI Ophthalmics, Inc. Clinically, silicone nasolacrimal intubations performed with the MASTERKA® have similar efficacy outcomes and safety as the predicate devices and other nasolacrimal intubation devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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FCI SAS (France Chirurgie Instrumentation)
c/o Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3308 Jefferson Avenue, Upper Level
Cincinnati, OH 45220

Re: K113536

Trade/Device Name: MASTERKA
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: July 23, 2012
Received: July 25, 2012

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

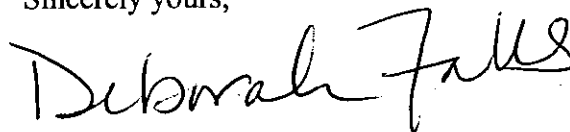
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K113536

Device Name: MASTERKA**Indications for Use:**

The MASTERKA® is a silicone intubation device indicated for use in the treatment of congenital lacrimal duct obstructions (stenosis of the valve of Hasner) in patients 12 months and older.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

D. Hall for C. Krawczyk
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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